AF IFW

TRANSMITTAL LETTER (General - Patent Pending)	Docket No. 112703-203

In Re Application Of: **Ream et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/990,628	November 13, 2001	S. Howard	29156	1615	4209

Title: **OVER-COATED CHEWING GUM FORMULATIONS**

COMMISSIONER FOR PATENTS:

Transmitted herewith is:

Transmittal of Appeal Brief (duplicate); Appeal Brief (7 pgs.) w/Exhibits A-D; Evidence Appendix (1 pg.); Claims Appendix (3 pgs.); Summary Appendix (2 pgs.); check in the amount of $500 - appeal brief; return receipt postcard.

in the above identified application.

- ☐ No additional fee is required.
- ☒ A check in the amount of is attached.
- ☒ The Director is hereby authorized to charge and credit Deposit Account No. **02-1818** as described below.
  - ☐ Charge the amount of
  - ☒ Credit any overpayment.
  - ☒ Charge any additional fee required.
- ☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Dated: November 15, 2005

Signature

Robert M. Barrett
Reg. No. 30,142

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

11/15/05
(Date)

Signature of Person Mailing Correspondence

Heather Foster

Typed or Printed Name of Person Mailing Correspondence

cc:

TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No. 112703-203

In Re Application Of: **Ream et al.**

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
09/990,628	November 13, 2001	S. Howard	29156	1615	4209

Invention: **OVER-COATED CHEWING GUM FORMULATIONS**

COMMISSIONER FOR PATENTS:

Transmitted herewith in triplicate is the Appeal Brief in this application, with respect to the Notice of Appeal filed on **September 15, 2005**

The fee for filing this Appeal Brief is: **$500.00**

☒ A check in the amount of the fee is enclosed.

☐ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **02-1818**

☐ Payment by credit card. Form PTO-2038 is attached.

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Signature

Dated: **November 15, 2005**

Robert M. Barrett
Reg. No. 30,142

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on

11/15/05
(Date)

Signature of Person Mailing Correspondence

Heather Foster

Typed or Printed Name of Person Mailing Correspondence

cc:

THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant(s): Ream, et al.
Appl. No.: 09/990,628
Conf. No.: 4209
Filed: November 13, 2001
Title: OVER-COATED CHEWING GUM FORMULATIONS
Art Unit: 1615
Examiner: S. Howard
Docket No.: 112703-203

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANTS' APPEAL BRIEF

Sir:

Appellants submit this Appeal Brief in support of the Notice of Appeal filed on September 15, 2005. This Appeal is taken from the Final Rejection dated June 17, 2005.

I. REAL PARTY IN INTEREST

The real party in interest for the above-identified patent application on appeal is Wm. Wrigley Jr. Company by virtue of an Assignment dated October 11, 2001, October 17, 2001 and October 30, 2001 and recorded at the United States Patent and Trademark Office at reel 012321, frame 0775.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative and the Assignee of the above-identified patent application note that there are no related appeals or interferences in this application.

III. STATUS OF CLAIMS

Claims 9-26 are pending in the above-identified patent application. Claims 9-26 are being appealed in this Brief. A copy of the appealed claims is provided in the Claims Appendix.

IV. STATUS OF AMENDMENTS

A Final Office Action was mailed on June 17, 2005. Appellants filed a Response to the Final Office Action on August 17, 2005. An Advisory Action was mailed on September 12, 2005. In the Advisory Action, the Response was considered but was deemed not to place the patent application in condition for allowance. A copy of the Final Office Action is attached as Exhibit A in the Evidence Appendix and a copy of the Advisory Action is attached as Exhibit B in the Evidence Appendix.

V. SUMMARY OF CLAIMED SUBJECT MATTER

A summary of the invention by way of reference to the drawings and specification for each of the independent claims (Claims 9 and 18) may be found in the Summary Appendix attached to this Brief.

Although specification citations are given in accordance with C.F.R. 1.192(c), these reference numerals and citations are merely examples of where support may be found in the specification for the terms used in this section of the Brief. There is no intention to suggest in any way that the terms of the claims are limited to the examples in the specification. As demonstrated by the references numerals and citations below, the claims are fully supported by the specification as required by law. However, it is improper under the law to read limitations from the specification into the claims. Pointing out specification support for the claim terminology as is done here to comply with rule 1.192(c) does not in any way limit the scope of the claims to those examples from which they find support. Nor does this exercise provide a mechanism for circumventing the law precluding reading limitations into the claims from the specification. In short, the references numerals and specification citations are not to be construed as claim limitations or in any way used to limit the scope of the claims.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 9-26 stand rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 5,665,406 to Reed, et al. ("*Reed*") in view of U.S. Patent No. 5,656,296 to Khan, et al. ("*Khan*").

A copy of *Reed* is attached as Exhibit C in the Evidence Appendix. A copy of *Khan* is attached as Exhibit D in the Evidence Appendix.

VII. ARGUMENT

A. LEGAL STANDARD FOR OBVIOUSNESS

Whether a claim is obvious is a question of law that is based on underlying factual inquiries including: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *In re Zurko*, 59 U.S.P.Q.2d 1693, 1696 (Fed. Cir. 2001).

The Patent Office has the initial burden of proving a *prima facie* case of obviousness and this burden remains until final decision. *Stratoflex, Inc. v. Aeroquip Corp.*, 218 U.S.P.Q. 871 (Fed. Cir. 1983). In making this determination, the question is not whether the differences between the prior art and the claims themselves would have been obvious, but whether the claimed invention as a whole would have been obvious to a person of ordinary skill in the art. *In re Dembiczak,* 50 U.S.P.Q.2d 1614, 1616 (Fed. Cir. 1999). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so, found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Kotzab*, 55 U.S.P.Q.2d 1313, 1317 (Fed. Cir. 2000).

The Federal Circuit has held that "obvious to try" is not the standard under 35 U.S.C. §103. *In re Roemer*, 59 U.S.P.Q.2d 1527, 1531 (Fed. Cir. 2001). "An obvious-to-try situation exists when a general disclosure may pique the scientist curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claim result would be obtained if certain directions were pursued." *In re Eli Lilly and Co.*, 14 U.S.P.Q.2d 1741, 1743 (Fed. Cir. 1990). Also, one cannot use "hindsight reconstruction to pick and choose among isolated disclosures in

the prior art" to re-create the claimed invention. *In re Fine*, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). Thus, the mere fact that the prior art can be combined to achieve Appellants' claimed invention is not enough to demonstrate obviousness. *In re Laskowski*, 10 U.S.P.Q.2d 1397 (Fed. Cir. 1989). Rather, the prior art, in its entirety, must provide the teaching to make the combination obvious. *In re Dance*, 48 U.S.P.Q.2d 1635, 1637 (Fed. Cir. 1998).

Of course, "a prior art reference is relevant for all that it teaches to those of ordinary skill in the art." *In re Fritch*, 23 U.S.P.Q.2d 1780, 1782 (Fed. Cir. 1992). In this regard, "a prior art reference may be considered to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the appellant." *In re Haruna*, 58 U.S.P.Q.2d 1517, 1522 (Fed. Cir. 2001). "If the examination at the initial stage does not produce a *prima facie* case of unpatentability, then without more the appellant is entitled to grant of the patent." *In re Oetiker*, 24 U.S.P.Q. 2d 1443, 1444 (Fed. Cir. 1992).

Further, it is improper to use an invention as a template for its own reconstruction based on hindsight knowledge of the patented invention when the prior art does not contain or suggest that knowledge. *Sensonics, Inc. v. Aerosonic Corp.*, 38 U.S.P.Q.2d 1551, 1554 (Fed. Cir. 1996). In this regard, the invention "must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made." *Id.* As such, the Federal Circuit has acknowledged the need for "rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999).

B. THE INDEPENDENT CLAIMS

Independent Claim 9 is directed to a chewing gum comprising a gum center and a coating that surrounds the gum center. The coating comprises a medicament that is designed to be delivered into the systemic system of a patient. The coating comprises at least 50% by weight of the chewing gum.

Independent Claim 18 is directed to a product including a medicament. The product is designed to function by being delivered through the systemic system of an individual. The product comprises a chewing gum center and a coating that at least substantially surrounds the

chewing gum center, comprising at least 50% by weight of the product. The coating comprises a medicament and a high-intensity sweetener.

C. THE REJECTIONS

In the Final Office Action, Claims 9-26 where rejected under 35 U.S.C. §103(a), as stated in Section VI above. Specifically, the claims were rejected over *Reed* in view of *Khan*. The Patent Office has maintained that it would have been obvious to one of ordinary skill in the art at the time of the invention to provide a pellet chewing gum having a coating with a medicament in the coating.

D. THE REJECTION OF CLAIMS 9-26 SHOULD BE REVERSED BECAUSE THE PATENT OFFICE HAS FAILED TO ESTABLISH A PRIMA FACIE CASE OF OBVIOUSNESS

Claims 9-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Reed* in view of *Khan*. As noted above, Claims 9 and 18 are independent, and the remaining claims depend upon these two claims. Accordingly, these claims are the focus of the below discussion. Appellants respectfully disagree with and traverse the rejection of the claims because the cited references should not be combined and, even if combined, do not disclose, teach or suggest the elements of the claimed invention.

As noted above, obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention. Here, in short, *Reed* and *Khan* would have to teach placing a medicament in the coating of a product such as a chewing gum. Such is simply not the case, as neither reference (alone or in combination) teaches or suggests a medicament in a coating. *Reed* teaches a chewing gum with a coating, but does not teach, disclose or suggest a medicament. *Khan* teaches a medicament, but teaches away from placing that medicament in a coating. *Khan* teaches systems having a core comprising a medicament and a waxy material, with a coating over the medicament. This is contrary to the benefits of Appellants' claimed invention which places the medicament in the coating to accelerate its release. As the primary focus of *Khan* is on the delayed, sequential or timed release of medicaments, it teaches away from the claimed invention. *Reed* combined with *Khan* does not result in a product having a medicament in the coating, and one of ordinary skill in the art would

not, in view of what *Khan* teaches, place a medicament in the coating. Likewise, one of ordinary skill could not take the *Khan* medicament (found in the center of the product) and place it in *Reed* and still acquire the claimed invention. Accordingly, one of skill in the art would not arrive at the claimed invention by combining *Reed* and *Khan*.

Further, without hindsight one of ordinary skill would not be motivated to combine the two references. *Reed* teaches a coated gum, while *Khan* teaches administration of sustained release medicaments. The two references are not in a related field, and would not attract the attention of the same artisan. There is simply no suggestion of the invention of Claims 9-26 in either of the cited art. Without the benefit of hindsight, one of skill simply would not combine the references.

The Patent Office has maintained that there is motivation to combine the references because both teach utilizing an "active agent." More particularly, the Patent Office states that the two references are combinable because they both teach "coating an active agent or a drug."

First, it appears that the Patent Office is basing its assertions on a mistaken view of Appellants' claimed invention. As noted above, the Final Office Action states that "...both Reed and Khan teach coating an active agent or a drug." However, Appellants submit that this is not the case. *Reed* does not teach, disclose or suggest a medicament at all, and certainly does not teach coating the active agent. *Khan* discloses placing a coating over a medicament or drug, but this differs notably from *Reed*. Furthermore, Appellants are not claiming "coating an active agent or a drug." Instead, the claimed invention teaches products made up of a coating *comprising* a medicament. As such, the two references are wholly unrelated both to one another and to the claimed invention, and one of ordinary skill in the art would not look to combine them to achieve the claimed invention.

Second, the "active agent" of *Reed*, namely hydrogenated isomaltulose, differs significantly from the medicament of *Khan*. Hydrogenated isomaltulose is a polyol—a sugar-alternative component—and is not a medicament as required by the claimed invention and as disclosed by *Khan*.

The term "medicament" is well-known, and is described throughout the specification of the application at issue, as well as *Khan*. In particular, columns 1 and 2 of *Khan*'s specification equates medicaments to drugs. Examples of such drugs include (but are not limited to) stimulants, analgesics, antibiotics, etc. Medicaments are agents used to treat diseases, for

prophylactic purposes, to enhance performance, or the like. *Reed* simply teaches hydrogenated isomaltulose—a component that replaces sugar. The hydrogenated isomaltulose is located in the chewing gum coating in *Reed*, but cannot be considered a "medicament." Instead, such a component improves the appearance, taste, texture, mouth feel and other desirable properties of hard coated chewing gums. Indeed, hydrogenated isomaltulose does not fall within the known definition of a medicament. Accordingly, one of ordinary skill in the art would not—and indeed could not validly—consider such an element a "medicament." Accordingly, there is no motivation to combine *Reed* and *Khan*.

As there is no disclosure, teaching or suggestion of Appellants' claimed invention in *Reed* and/or *Khan*, even if the references are combined, Appellants respectfully submit that the claimed invention is not obvious.

VIII. CONCLUSION

Appellants respectfully submit that Claims 9-26 are not rendered obvious by the cited references under 35 U.S.C. §103(a). Accordingly, Appellants respectfully submit that the rejection of pending Claims 9-26 is erroneous in law and fact and should be reversed by the Board.

Respectfully submitted,

BELL, ~~BOYD &~~ LLOYD LLC

BY _____

Robert M. Barrett
Reg. No. 30,142
Customer No.: 29156

Dated: November 15, 2005

CLAIMS APPENDIX

PENDING CLAIMS ON APPEAL OF U.S. PATENT APPLICATION SERIAL NO. 09/990,628

9. A chewing gum comprising:

a gum center; and

a coating comprising a medicament that surrounds the gum center, the coating comprising at least 50% by weight of the chewing gum product, the medicament being designed to be delivered into the systemic system of a patient.

10. The chewing gum of Claim 9 wherein the medicament is selected from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; stimulants; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; and cardiovascular agents.

11. The chewing gum of Claim 9 wherein the coating includes a sufficient amount of taste masking agent to provide acceptable organoleptic properties.

12. The chewing gum of Claim 11 wherein the taste masking agent is selected from the group consisting of: zinc gluconate, ethyl maltol, glycine, acesulfame-k, aspartame; saccharin; fructose; xylitol; isomalt; maltitol; spray dried licorice root; glycerrhizine; sodium gluconate; glucono delta-lactone; ethyl vanillin; dextrose; sucralose; vanillin; and ethyl maltol.

13. The chewing gum of Claim 11 wherein the taste masking agent comprises approximately 30% to about 99% by weight of the coating.

14. The chewing gum of Claim 9 wherein the coating includes approximately 0.5% to about 5% by weight of a high-intensity sweetener chosen from the group consisting of aspartame, sucralose, saccharine, and acesulfame-k.

15. The chewing gum of Claim 9 wherein the gum center includes at least 50% by weight water-insoluble gum base.

16. The chewing gum of Claim 9 wherein the coating does not have a shellac layer.

17. The chewing gum of Claim 9 wherein the gum center and coating are sugar-free.

18. A product including a medicament that is designed to function by being delivered through the systemic system of an individual comprising:

a chewing gum center; and

a coating that at least substantially surrounds the chewing gum center and comprises a medicament and a high-intensity sweetener, the coating comprising at least 50% by weight of the product.

19. The product of Claim 18 wherein the medicament is selected from the group consisting of: analgesics; muscle relaxants; antibiotics; antivirals; stimulants; antihistamines; decongestants; anti-inflammatories; antacids; psychotherapeutic agents; insulin; vitamins; minerals; and cardiovascular agents.

20. The product of Claim 18 wherein the coating includes a sufficient amount of taste masking agent to provide acceptable organoleptic properties.

21. The product of Claim 18 wherein the taste masking agent is selected from the group consisting of: zinc gluconate, ethyl maltol, glycine, acesulfame-k, aspartame; saccharin; fructose; xylitol; isomalt; maltitol; spray dried licorice root; glycerrhizine; sodium gluconate; glucono delta-lactone; ethyl vanillin; dextrose; sucralose; vanillin; and ethyl maltol.

22. The product of Claim 18 wherein the taste masking agent comprises approximately 30% to about 99% by weight of the coating.

23. The product of Claim 18 wherein the coating includes approximately 0.5% to about 5% by weight of a high-intensity sweetener chosen from the group consisting of aspartame, sucralose, saccharine, and acesulfame-k.

24. The product of Claim 18 wherein the coating comprises at least 70% by weight powder when it is applied to the gum center.

25. The product of Claim 18 wherein the product is sugar-free.

26. The product of Claim 18 wherein the coating does not have a shellac layer.

EVIDENCE APPENDIX

EXHIBIT A: Final Office Action mailed on June 17, 2005.

EXHIBIT B: Advisory Action mailed on September 12, 2005.

EXHIBIT C: U.S. Patent No. 5,665,406 to Reed, et al. ("*Reed*") cited by the Patent Office in the Office Action mailed on March 23, 2004, the first Final Office Action mailed August 26, 2004, the Office Action mailed December 22, 2004, and the Final Office Action mailed June 17, 2005.

EXHIBIT D: U.S. Patent No. 5,656,296 to Khan, et al. ("*Khan*") cited by the Patent Office in the Office Action mailed on March 23, 2004, the first Final Office Action mailed August 26, 2004, the Office Action mailed December 22, 2004, and the Final Office Action mailed June 17, 2005.

SUMMARY APPENDIX

Claim 9	Drawings	Specification
A chewing gum comprising:	Figure 1	Page 4, ln. 10-20; Examples.
a gum center; and	Figure 1	Page 4, ln. 23-25; Page 15, ln. 5- Page 18, ln. 10; Examples.
a coating comprising a medicament that surrounds the gum center, the coating comprising at least 50% by weight of the chewing gum product, the medicament being designed to be delivered into the systemic system of a patient.	Figure 1	Page 1, ln. 11-13; Page 4, ln. 25-27; Page 5, ln. 23-31; Page 9, ln. 5-20; Examples.

Claim 18	Drawings	Specification
A product including a medicament that is designed to function by being delivered through the systemic system of an individual comprising:		Page 1, ln. 11-13; Page 4, ln. 9-10; Page 12, ln. 5-16.
a chewing gum center; and	Figure 1	Page 4, ln. 23-25; Page 15, ln. 5- Page 18, ln. 10; Examples.
a coating that at least substantially surrounds the chewing gum center and comprises a medicament and a high-intensity sweetener, the coating comprising at least 50% by weight of the product.	Figure 1	Page 1, ln. 11-13; Page 4, ln. 25-27; Page 5, ln. 23-31; Page 9, ln. 5-20; Examples.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,628	11/13/2001	Ronald L. Ream	112703-203	4209

29156 7590 06/17/2005

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER	
HOWARD, SHARON LEE	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 06/17/2005

DUE: 9/17/05

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/990,628	REAM ET AL.	
	Examiner	Art Unit	
	Sharon L. Howard	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Receipt of the response to the office action and the remarks filed on 3/24/05 have been acknowledged. Claims 9-26 remain pending in this application.

Claim Rejections - 35 USC § 103

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-26 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Reed et al. (USP 5,665,406) in view of Khan et al. (USP 5,656,296).

Reed teaches a pellet chewing gum which is coated with one or more coats of a polyol such as maltitol, lactitol and erythritol. Reed teaches that the chewing gum includes a gum center and an outer coating. Reed teaches that the gum center constitutes from about 35 to about 90 weight percent of the chewing gum product. The gum center which is sugarless comprises xylitol, maltitol and/or sorbitol. The outer coating contains from about 50 to about 100 weight percent of two polyols. See the abstract and see col.5, lines 5-25. Reed also teaches that the coating may also contain

from about 0.05 to about 0.3 weight percent of artificial sweeteners such as aspartame, acesulfame-K, saccharin and suralose. See col.7, lines 52-55 and col.8, lines 1-6. The gum base contains from about 10 to about 50% by weight of the chewing gum center. See col.8, lines 50-59. The reference clearly shows a chewing gum pellet which is coated with a polyol, having a sugarless gum center.

Reed does not teach the particular medicament.

However, Khan teaches drug delivery systems containing a core which comprises a medicament, including a waxy material and a coating layer over the core. See col.2, liens 46-51. Khan teaches medicaments such as analgesics, anti-inflammatory agents, cardiovascular preparations, decongestants and vitamins and minerals. See col.3, lines 24-51. Khan teaches that the coating layer of the drug delivery system may also contain sweetening agents and active agents. See col.7, lines 1-6.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the particular medicament taught by Khan in the Reed reference, for the purpose of delivering medicaments to the outer layer.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,298,263 teaches that the ingredient isomaltulose is a medicament.

Response to Arguments

Applicant's arguments filed 3/24/05 have been fully considered but they are not persuasive. Applicant argues that there is no suggestion or motivation to combine the

cited references to obtain the claimed invention, and even if combinable, all of the claimed elements are not taught or suggested by the cited references. There is no suggestion or motivation to combine the cited references to obtain the claimed invention. There is no direction provided in the cited references suggesting how they should be combined to obtain the claimed invention. Indeed, Applicants respectfully submit that it is only with an improper hindsight reconstruction of Applicant's claimed invention that the Patent Office is able to attempt to piece together a rejection of the claims. Applicants also respectfully submit that, even if combinable, the cited references do not disclose all of the claimed elements. For instance, *Reed* fails to disclose a medicament in the coating or even any medicament anywhere in the product. *Khan* fails to remedy the deficiencies of *Reed.* Contrary to the present claims, *Khan* fails to disclose or suggest a medicament in the coating. Indeed, *Khan* teaches away from this concept. Nowhere in the specification does *Khan* specifically disclose or suggest a medicament in the coating. In contrast, the present invention places the medicament within the coating , which is the exact opposite concept of *Khan.* Although the Patent Office alleges that *Khan* teaches that the coating layer of the drug deliver system may also contain sweetening agents and active agents, these ingredients are not medicaments. One having ordinary skill in the art would not consider the inert ingredients as medicaments. Further, *Khan* clearly distinguishes its medicaments by listing them. Thus, if anything, *Khan* can be said to teach away from the claimed invention. For the reasons discussed above, the combination of *Reed* in view of *Khan* does not teach, suggest, or even disclose the claimed invention, and thus, fails to

render the claimed subject matter obvious for at least these reasons. Accordingly, Applicants respectfully request that the obviousness rejections with respect to Claims 8-26 be reconsidered and the rejections be withdrawn.

In response to the arguments, Reed ('406) does teach coating a chewing gum with an active agent such as hydrogenated isomaltulose (see col.6, lines 54-61). There is motivation for combining the references since both Reed and Khan teach coating an active agent or a drug. Thus, the claims do render applicant's claims obvious.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Howard whose telephone number is (571) 272-0596. The examiner can normally be reached on 9:00am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharon Howard

Sharon Howard
June 8, 2005

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Notice of References Cited

Application/Control No.	Applicant(s)/Patent Under Reexamination	
09/990,628	REAM ET AL.	
Examiner	Art Unit	Page 1 of 1
Sharon L. Howard	1615	

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
	A	US-5,298,263	03-1994	Yatka et al.	426/5
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/990,628	11/13/2001	Ronald L. Ream	112703-203	4209

29156 7590 09/12/2005

BELL, BOYD & LLOYD LLC
P. O. BOX 1135
CHICAGO, IL 60690-1135

EXAMINER	
HOWARD, SHARON LEE	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief

Application No.	Applicant(s)	
09/990,628	REAM ET AL.	
Examiner	**Art Unit**	
Sharon L. Howard	1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 August 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: 9-26.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Continuation of 11. does NOT place the application in condition for allowance because: The broad scope of applicants' claims permit the presence of hydrogenated isomaltulose. Applicant please note that the argument that hydrogenated isomaltulose is not an active agent, but a polyol (a sugar-alternative component) is NOT persuasive.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600